

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of melatonin treatment in patients with Irritable Bowel Syndrome (IBS)

Protocol summary

Summary

Purpose: Efficacy of melatonin to improve gastrointestinal symptoms in patients with Irritable Bowel Syndrome (IBS) in comparison with placebo group.

Method: First, among patients who referred to Amir hospital in Arak, IBS patients would be diagnosed by the gastroenterologist, using rome III criteria. Then, the patients randomly will be divided into two group of 32. One group would be administered melatonin and the other group would be administered placebo. Before starting the treatment, for registering essential information, patients should complete a questionnaire designed for this purpose. Treatment of two groups will be continued for 8 weeks, then patients will be recalled and they should complete a questionnaire for other essential information for the study.

Inclusion Criteria: patients with IBS according to rome III criteria; Lack of coincident disease; Not using other therapies for treatment of IBS during last month.

Exclusion Criteria: Non cooperative patients; Substance addicted patients.

Intervention: Information and variables registered in the two questionnaire before and after treatment would be compared and assessed, and the effect of melatonin on patients would be assessed according to gender, age, and symptoms like abdominal pain, bloating and changes in bowel habit.

Main outcome variable: The effect of melatonin on quality of life improvement of IBS patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012532186N1**

Registration date: **2017-09-24, 1396/07/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-24, 1396/07/02

Registrant information

Name

Hossein Rashvand

Name of organization / entity

Arak medical university

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of melatonin treatment in patients with Irritable Bowel Syndrome (IBS)

Public title

The effect of melatonin treatment in patients with Irritable Bowel Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Irritable Bowel Syndrome (IBS) based on Rome III criteria; Lack of comorbidity including anemia, blood in the stool, significant weight loss, nocturnal diarrhea, Inflammatory Bowel Disease (IBD); previous abdominal surgery; diabetes; thyroid disorders; do not use antibiotic in the last month; do not take drug for IBS treating in the last month. Exclusion criteria: lack of patient collaboration; drug addiction; any risk of heart disease; neurological and psychological disorder; gastrointestinal and liver disease; pregnancy; any kind of malignancy

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization method is randomized block design.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences

Street address

Mailbox646; Allamolhoda St; Shahid Shiroudi St

City

Arak

Postal code

3819693345

Approval date

2016-07-18, 1395/04/28

Ethics committee reference number

IR.ARAKMU.REC.1395.147

Health conditions studied

1

Description of health condition studied

Irritabile Bowel Syndrome

ICD-10 code

K58.9, k58

ICD-10 code description

Irritable bowel syndrome with diarrhoea, Irritable bowel syndrome without diarrhoea

Primary outcomes

1

Description

The effect of melatonin on the abdominal pain in patients with irritable bowel syndrome

Timepoint

Before and 8 weeks after receiving a daily dose of 3 mg melatonin

Method of measurement

questionnaire

2

Description

The effect of melatonin on the abdominal bloating in patients with irritable bowel syndrome

Timepoint

Before and 8 weeks after receiving a daily dose of 3 mg melatonin

Method of measurement

questionnaire

3

Description

The effect of melatonin on the number of bowel movements and stool constipation in patients with irritable bowel syndrome

Timepoint

Before and 8 weeks after receiving a daily dose of 3 mg melatonin

Method of measurement

questionnaire

Secondary outcomes

1

Description

The effect of melatonin on the quality of life in patients with irritable bowel syndrome

Timepoint

Before and 8 weeks after taking 3 mg of melatonin tablets

Method of measurement

questionnaire

Intervention groups

1

Description

In intervention group, melatonin would be given to patients in the form of 3 milligram tablets made by Nature Med for 8 weeks.

Category

Treatment - Drugs

2

Description

In control group, placebo would be given to patients in the form of tablets similar to melatonin tablets for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Hospital GI Clinic

Full name of responsible person

Hossein Rashvand

Street address

Amir Medical and Educating Center; Basij SQ

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Arak University of Medical Sciences

Full name of responsible person

Hossein Rashvand

Street address

Amir Medical and Educating Center; Basij SQ

City

Arak

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Arak University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University Of Medical Sciences

Full name of responsible person

Hossein Rashvand

Position

Assistant Professor of Internal Medicine

Other areas of specialty/work

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Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

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Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty